

REMARKS

The April 1, 2009 Official Action and the reference cited therein have been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

As a preliminary matter, Applicants acknowledge the Examiner's request to cancel claims withdrawn from consideration in the present application. These claims will be cancelled upon notification of allowable subject matter.

The Examiner has asserted that newly presented claims 38 and 42 are directed to an invention that is independent or distinct from the invention originally claimed because these claims require that a tumor antigen be expressed. Inasmuch as claim 1 is generic, encompassing any antigen of interest, and claims 38 and 42 depend directly from claim 1, Applicants are unclear as to the Examiner's rationale for restricting out these claims. The Examiner is respectfully requested to reconsider this requirement for restriction.

In the Official Action, the Examiner has rejected claims 1, 2, 7, 10, 13, 14, 39-41, 43, and 45 under 35 U.S.C. §102(b) as allegedly anticipated by Rovinski et al.

Applicants respectfully submit that the claims as presently amended are in condition for allowance. The above-noted rejection under 35 U.S.C. §102 is, therefore, respectfully traversed.

**THE CLAIMS AS AMENDED ARE NOVEL
OVER THE DISCLOSURE IN US PATENT APPLICATION
2002/0051770 TO ROVINSKI ET AL.**

The present invention relates to a heterologous prime-boost immunization strategy where an infectious, replication deficient lentivirus vector is used as a carrier of nucleic acid encoding the antigen of interest in either the priming phase or the boosting phase, but not both. The lentivirus

expressing the antigen may be contained within an antigen presenting cell.

As the examiner states, Rovinski et al. discloses a prime-boost immunization strategy which uses plasmids encoding HIV-like particles as the priming material and non-infectious, non-replicating HIV-like particles encoding the antigen as the boosting material. It is apparent from the reading of Rovinski et al that it is an essential feature of their disclosure that the VLP is non-infectious. Indeed, on page 2 paragraph [0017], they suggest further ways in which the particles can be mutated further to reduce potential infectivity.

In complete contrast, the presently claimed method encompasses use of infectious, replication-defective lentivirus which infect APCs in vivo. Claim 1 has been amended to recite this feature. This amendment is fully supported by the application as filed. See for example, page 2, lines 33 to 35 which make clear that the lentivirus must be capable of infecting antigen presenting cells, e.g. dendritic cells and induce presentation of an antigen encoded by the lentivirus to prime a T cell response. Please also see page 20, lines 21 to 26 which reiterate that the lentivirus vectors of the invention are infectious and replication-defective. That is, they can infect cells but the infection is attenuated and does not give rise to progeny virus, especially replication-competent progeny virus.

In order to support a rejection of claims under 35 U.S.C. §102, a reference must **identically** disclose each and every element of the claims. Applicants respectfully submit that for at least the reasons set forth above, the presently claimed method is not anticipated by the disclosure in Rovinski et al. Accordingly, the rejection under 35 U.S.C. §102(b) is inappropriate and should be withdrawn.

CONCLUSION


It is respectfully requested that the amendments presented herewith be entered in this application, since the

amendments are primarily formal, rather than substantive in nature. This amendment is believed to clearly place the pending claims in condition for allowance. In any event, the claims as presently amended are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

In view of the amendments presented herewith, and the foregoing remarks, it is respectfully urged that the rejections set forth in the April 1, 2009 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to call the undersigned at the phone number given below.

Respectfully submitted,
DANN, DORFMAN, HERRELL AND SKILLMAN
A Professional Corporation

By 
Kathleen D. Rigaut, Ph.D., J.D.
PTO Registration No. 68,047

Telephone: (215) 563-4100
Facsimile: (215) 563-4044